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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/577,791

08/18/2006

Hiroshi Yokota

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KILYK & BOWERSOX, P.L.L.C.  
400 HOLIDAY COURT  
SUITE 102  
WARRENTON, VA 20186

EXAMINER

HIRIYANNA, KELAGINAMANE T

ART UNIT

PAPER NUMBER

1633

MAIL DATE

DELIVERY MODE

04/02/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/577,791	<b>Applicant(s)</b> YOKOTA ET AL.	
	<b>Examiner</b> KELAGINAMANE T. HIRIYANNA	<b>Art Unit</b> 1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 28 April 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-20 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

The inventions as claimed are classified into following groups:

- I. Claim 1, A DNA consisting of a nucleotide sequence as set forth in AEQ ID NO:1
- II. Claim 2, A DNA in which %' end of DNA consisting of a nucleotide sequence of SEQ ID NO:1 is added to a 3'end of nucleotide sequence as set forth in SEQ ID NO:2.
- III. Claim 3 A DNA consisting of a nucleotide sequence as set forth in SEQ ID NO:3.
- IV. Claim 3 A DNA consisting of a nucleotide sequence as set forth in SEQ ID NO:4.
- V. Claim 3 A DNA consisting of a nucleotide sequence as set forth in SEQ ID NO:5.
- VI. Claim 3 A DNA consisting of a nucleotide sequence as set forth in SEQ ID NO:6.
- VII. Claim 4-5 and 7 A DNA consisting of a nucleotide sequence as set forth in SEQ ID NO:1 which has a transcriptional activity.
- VIII. Claim 6 An apparatus for regulating gene expression comprising the DNA consisting of a nucleotide sequence as set forth in SEQ ID NO:1.
- IX. Claim 8-13 A vector comprising the DNA consisting of a nucleotide sequence as set forth in SEQ ID NO:1.
- X. Claim 14-15 A transformant which is transformed with the vector comprising a DNA consisting of a nucleotide sequence as set forth in SEQ ID NO:1.
- XI. Claim 16-17 A method of preparing the DNA consisting of a nucleotide sequence as set forth in SEQ ID NO:1 by reacting with SEQ ID NO:2.

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XII. Claim 18 A method of regulating an amount of expression of a gene where in the method comprises using the DNA consisting of a nucleotide sequence as set forth in SEQ ID NO:1.

XIII. Claim 19 A method of producing a protein the DNA consisting of a nucleotide sequence as set forth in SEQ ID NO:1, a DNA comprising a structural gene, a vector, a transformant.

XIV. Claim 20 A kit comprising at least the DNA consisting of a nucleotide sequence as set forth in SEQ ID NO:1, as structural gene, a vector or a transformant with ssaid vector.

The inventions listed as Groups I-XIV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: a) The feature linking claims 1-20 i.e., namely SEQ ID NO:1 is clearly interrupted in claim 3. The invention as whole thus lacks unity under PCT rule hence a restriction as indicated above is proper. The mode of operation, and the effects evaluated in each of the above invention are distinct and different from the other. Therefore, a search and examination for the patentability of the above inventive groups together would generate an undue search burden on the examiner. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

USPTO has revised its official position on nucleotide sequences, rescinding the 1996 waiver for examining up to 10 nucleic acid sequences Published March 27, 2007 in the Official Gazette:

The United States Patent and Trademark Office (office) published an Official Gazette notice in November of 1996 providing a partial waiver of the requirements for restriction pursuant to 37 CFR 1.141 et. seq. and for unity of invention determinations pursuant to 37 CFR 1.475 et. eq. See Examination of Patent Applications Containing Nucleotide Sequences, 1192 Off. Gaz. Pat. Office 68 (Nov. 19, 1996) (1996 Notice). The 1996 Notice permitted examination of a reasonable number, normally up to ten independent and distinct molecules described by their nucleotide sequence in a single patent application. The office has reconsidered the policy set forth in the 1996 Notice in view of changes in the complexity of applications filed, the types of inventions claimed and the state of the prior art in this technology since that time. Because of these changes, the search and examination of up to ten molecule described by their nucleotide sequence often consumes a disproportionate amount of Office resources over that

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expended in 1996. Consequently, with this Notice the Office rescinds the partial waiver of 37 CFR 1.141 et seq. for restriction practice in national applications filed under 35 U.S.C. 111(a), and 37 CFR 1.475 et seq. for unity of invention determinations in both PCT international applications and the resulting national stage applications under 35 U.S.C. 371. This Notice is effective immediately and is applicable to all pending applications. Note, however, that supplemental restriction requirements will not be advanced in applications that have already received an action on their merits in the absence of extenuating circumstances. Thus it is the official opinion of the USPTO that searching more than one sequence has indeed become a burden to the office.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the response to this requirement to be complete must

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include an election of the invention to be examined even though the requirement be traversed. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner *Kelaginamane Hirianna Ph.D.*, whose telephone number is (571) 272-3307. The examiner can normally be reached Monday through Thursday from 9 AM-7PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *Joseph Woitach Ph.D.*, may be reached at (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). When calling please have your application serial number or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. For all other customer support, please call the USPTO call center (UCC) at (800) 786-9199.

/Robert M Kelly/

Primary Examiner, Art Unit 1633